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NOTES

Reviving Lazarus: Status of the FDA Compliance Defense after *Bates v. Dow Agrosciences* and the New FDA Regulations

Jason T. Ams¹

I. INTRODUCTION

Pharmaceutical products liability cases continue to flow into courtrooms across the United States, burdening both the courts and the pharmaceutical industry.² The industrial impact of this litigation is readily apparent. For instance, pharmaceutical giant Merck announced that it will close five manufacturing plants and lay off 7,000 employees,³ over a tenth of its workforce, due in part to thousands of lawsuits over Vioxx.⁴ Further, Merck will have to cope with the exponential cost of litigation and divert resources away from valuable medical research projects. These effects, combined with a simultaneous call by various consumer advocacy groups to lower the cost of medications,⁵ have caused the major pharmaceutical companies to search for ways to remove themselves from costly litigation.

Pharmaceutical products liability cases based on manufacturing or design defects are few; instead, the vast majority of the cases center upon the "failure to warn" theory.⁶ Attorneys for the pharmaceutical companies, and notably for the company Pfizer, have attempted to combat "failure to warn" claims with a federal preemption defense, sometimes referred to as the "FDA compliance" defense.⁷ The theory is based on federal preemption of tort claims through compliance with Food and Drug Administration ("FDA") regulations or by FDA declarations on the issue. Historically, courts refused to recognize the defense. Two key events have occurred, however, that inject new life into the issue and bring the "FDA compli-

¹ J.D. Candidate, 2007, University of Kentucky College of Law; B.S. Political Science, 2004, Murray State University.

² Diane E. Lifton & Michelle M. Bufano, *A Call for Continued State Law Tort Reform*, PHARMACEUTICAL & MED. DEVICE L. BULL., Mar. 2004, at 1.

³ Alex Berenson, *Revamping at Merck to Cut Costs*, N.Y. TIMES, Nov. 29, 2005, at C1.

⁴ *Id.*

⁵ *Id.*

⁶ Lifton & Bufano, *supra* note 2, at 1.

⁷ *Id.*

ance” defense to the forefront of pharmaceutical “failure to warn” products liability cases.

First, the FDA filed an amicus curiae brief in *Motus v. Pfizer, Inc.*⁸ that supported federal preemption of a state tort claim. The brief stated that the FDA had previously considered the warnings insisted upon by the plaintiff in their “failure to warn” claim and rejected them.⁹ Had Pfizer added the warnings to the FDA-approved warnings, the company would have been subject to misbranding provisions under the Food, Drug, and Cosmetics Act (“FDCA”),¹⁰ the governing organic statute of the FDA and its prescription drug labeling efforts.

The Ninth Circuit Court of Appeals upheld the summary judgment dismissing the suit in favor of Pfizer, but it did not reach the issue of preemption.¹¹ Two subsequent cases utilized the *Motus* brief to find federal preemption of the state “failure to warn” claims, but several other courts refused to follow suit. Following the U.S. Supreme Court case of *Bates v. Dow Agrosciences, LLC*,¹² it seemed that although FDA regulatory warnings alone would not allow for preemption, state tort liability might be preempted when something more (such as the *Motus* brief) was both present and timely.¹³ Before this theory could be tested further, however, the FDA upped the ante.

The second event occurred when the FDA announced a new regulatory system for prescription drug warning labels on January 24, 2006. The purpose of the new regulations was to greatly simplify the existing labels by adding a “Highlights” section for major indications, effects, and directions, along with several other alterations. During promulgation of this rule, “some manufacturers expressed concerns that, by highlighting selected information . . . to the exclusion of information not highlighted, they make themselves more vulnerable to product liability claims.”¹⁴

The FDA responded to these criticisms by “tak[ing] steps to enhance the prominence of the Highlights limitation statement.”¹⁵ While believing “that this limitation statement will help to ensure that the labeling will be considered in its entirety in any products liability action,” the FDA also

8 *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004).

9 Amicus Brief for the United States in Support of the Defendant-Appellee and Cross-Appellant, *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004) (Nos. 02-55372, 02-55498), 2002 WL 32303084.

10 Amicus Brief for the United States, *supra* note 9, at 15; *see also* 21 U.S.C. §§ 301–99 (2000).

11 *Motus*, 358 F.3d 659.

12 *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005).

13 *Id.* at 452–53.

14 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 21 C.F.R. § 201.56.

15 *Id.* at 3933.

declared that it believed “that under existing preemption principles such product liability claims would be preempted.”¹⁶ The FDA has maintained that this is simply a statement of its long-held policy, and many groups have asserted that the preemption assertion appears in the preamble to the actual rule, thus holding no legal force.¹⁷ Both sides of the issue are still highly concerned. The pharmaceutical industry feels they are being made vulnerable to increased litigation despite the FDA’s assurances; conversely, plaintiffs’ lawyers, consumer advocacy groups, and legislators alternate between asserting that the FDA lacks the power to make such assurances and accusing the FDA of stripping prescription drug recipients of essential rights.

The following Note analyzes whether the FDA regulations actually preempt state tort law. Part II provides a brief overview of the technical requirements for compliance with the FDA warnings requirements.¹⁸ Part III examines the history of preemption through compliance with the FDCA, both in general and in connection with the *Motus* brief.¹⁹ Part IV examines the impact of the recent United States Supreme Court case of *Bates v. Dow Agrosciences, LLC* on pharmaceutical products liability “failure to warn” cases as applied in *Rite Aid Corp. v. Levy-Gray*.²⁰ Finally, Part V compares the conclusions of law leading up to the recent FDA assertion and the impact of the statements by the FDA on the status of the law.²¹

II. TECHNICAL REQUIREMENTS FOR FDA APPROVAL

For a drug to be approved by the FDA, it must be shown that the “drug is safe for use and . . . such drug is effective in use.”²² The pharmaceutical company demonstrates this requirement through a “new drug application” (“NDA”) that contains “all of the animal, pharmacologic, and clinical studies and evaluations pertinent to the safety and efficacy of the drug.”²³ While a detailed list of the numerous requirements for FDA approval is beyond the scope of this Note, the process has been defined as a “unique” one, “required by law before a prescription drug can be marketed, [including]

¹⁶ *Id.*

¹⁷ *Senate Democrats May Block FDA Rx Labeling Rule with Legislation*, FDA WEEK, Jan. 20, 2006, 2006 WLNR 1097774.

¹⁸ See *infra* notes 22–31 and accompanying text.

¹⁹ See *infra* accompanying notes 32–99 and accompanying text.

²⁰ *Rite-Aid Corp. v. Levy-Gray*, 876 A.2d 115 (Md. Ct. Spec. App. 2005), *aff’d*, 894 A.2d 563 (Md. 2006); see also *infra* notes 100–16. and accompanying text.

²¹ See *infra* notes 117–48 and accompanying text.

²² 21 U.S.C. § 355(b)(1)(A) (2000).

²³ Wilfred P. Coronato & Stephen Lanza, *The Fracture that Will Not Heal: the Landscape of Federal Preemption in the Fields of Medical Devices, Prescription and Over-The-Counter Drugs Ten Years after Medtronic, Inc. v. Lohr*, SLO38 ALI-ABA 365, 383 (2005) (citing 21 U.S.C.A. § 355(b) & (d) (West 2006)).

the FDA's continued involvement in evaluating product labeling during the post-marketing phase."²⁴

The post-marketing phase is typically the time period involved in litigation, and it usually centers on some side effect that has surfaced and injured a plaintiff after initial marketing but before the labeling on the drug has been changed. The regulations for updating a warning label require an applicant to "notify the FDA about each change in condition established in an approved [NDA] beyond the variations already provided for in the [NDA]."²⁵ A specific set of "changes" to the warning label are designated as "major changes" and must be sent to the FDA as a supplemental submission for approval before the manufacturer may employ them on the packaging.²⁶ These mandatory submissions are not required for "changes in labeling [that] . . . add or strengthen a contraindication, warning, precaution, or adverse reaction."²⁷ On their face, the regulations do not appear to support a federal preemption defense as they specifically allow additional warnings to be included in the warnings package by the manufacturer.

Notwithstanding this language, pharmaceutical companies continued to attempt a preemption defense, citing the broad and inclusive role of the FDA in authorizing new drugs, the continued surveillance and reporting requirements concerning existing drugs, and the ability of the FDA to force withdrawal of the drug accompanied by possible criminal and/or civil penalties when either new information arose concerning the drug's properties or the drug was mislabeled in violation of the FDA mandate.²⁸ Due to this heavy regulation, the companies claimed, a state court plaintiff commencing a "failure to warn" claim would meet the requirements for conflict preemption and be barred by the applicable federal law. Courts strongly resisted this defense in general, and they almost universally denied a general "preemption" defense for warning labels under the FDCA.²⁹ The successes were rare and often accompanied by other, more established grounds for the ruling.³⁰ New life, however, was breathed into the issue by a FDA amicus curiae brief in *Motus v. Pfizer, Inc.*³¹

24 Lifton & Bufano, *supra* note 2, at 1.

25 21 C.F.R. § 314.70(a)(1) (2006).

26 21 C.F.R. § 314.70(b)(1) (2006).

27 21 C.F.R. § 314.70(c)(6)(iii)(A) (2006).

28 Lifton & Bufano, *supra* note 2, at 2.

29 Coronato & Lanza, *supra* note 23, at 384.

30 See, e.g., *Ehlis v. Shire Richwood, Inc.*, 233 F. Supp. 2d 1189 (D.N.D. 2002), *aff'd*, 367 F.3d 1013 (8th Cir. 2004).

31 *Motus v. Pfizer, Inc.*, 358 F.3d 659 (9th Cir. 2004); Amicus Brief for the United States, *supra* note 9.

III. THE *MOTUS* BRIEF AND THE AFTERMATH

A. *Previous Preemption Efforts*

Prior to the *Motus* case, few courts found state pharmaceutical products liability claims preempted by FDA regulations promulgated under the FDCA. An example of one of the rare cases that allowed preemption was *Ehlis v. Shire Richwood, Inc.*³² The pharmaceutical companies involved set forth all forms of preemptive arguments, including express preemption and every form of implied preemption. The court concentrated on the ability of a pharmaceutical company to only temporarily alter the warning until the FDA could review and approve the change. It also noted the extensive review of *Medtronic, Inc. v. Lohr*³³ and preemption law conducted by the Eighth Circuit in *Brooks v. Howmedica, Inc.*³⁴ concerning a similar situation under the Medical Device Amendments (“MDA”).³⁵

Ultimately, the district court concluded that the plaintiff failed to distinguish the MDA from the FDCA and “[was] not convinced that preemption would not apply in this case.”³⁶ This ruling was in the alternative to other, more accepted arguments, and it did not lead to more preemption findings in that jurisdiction. It was later affirmed on the more accepted argument of the “learned intermediary rule,” and the appellate court declined to address the preemption issue.³⁷

The *Motus* case, although not resolved on the federal preemption issue, awakened a new theory for the defense in 2000. The FDA *directly* intervened in the *Motus* case by filing an amicus brief declaring that the warning promulgated by the plaintiff would have “misbranded” the drug had it been applied to warnings included for Zolof. ³⁸ The same amicus brief

32 *Ehlis*, 233 F. Supp. 2d 1189.

33 *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Medtronic* is a principal federal preemption case that addressed potential federal preemption concerns over medical devices under the Medical Device Amendments (“MDA”). The court ruled against preemption, finding that state actions that were substantially equivalent to the federal requirements were not preempted and instead simply gave an alternative for litigants to pursue. Specifically, the court held that the federal government’s requirements in the MDA were too “generic” in nature to be preemptive, “quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.” *Id.* at 501. The *Medtronic* case is one of several that contribute to the current shape of federal preemption law, and an extended discussion of all its points and conclusions is beyond the scope of this Note.

34 *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001).

35 *Id.* at 791.

36 *Ehlis*, 233 F. Supp. 2d at 1198.

37 *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1015, 1019 (8th Cir. 2004).

38 Amicus Brief for the United States, *supra* note 9, at 15–22.

was used successfully in *Dusek v. Pfizer, Inc.*³⁹ later in 2000 and *Needleman v. Pfizer, Inc.*⁴⁰ in 2002. The brief was disregarded by courts beginning later in 2002 and continuing through 2005.

B. Motus v. Pfizer, Inc. and Direct Intervention by the FDA

Plaintiff Flora Motus brought suit against Pfizer, alleging among other claims that Pfizer had “negligently . . . fail[ed] to adequately warn the medical community, the general public and plaintiff’s decedent, Victor Motus [husband to Plaintiff] . . . of the dangers, contraindications and side effects . . . of Zoloft.”⁴¹ In particular, Pfizer had failed to warn that use of Zoloft “can cause the user to become violent and suicidal.”⁴² Shortly after beginning use of Zoloft in November of 1998, Victor Motus committed suicide.⁴³ Pfizer sought partial summary judgment on the “failure to warn” claim, and it based its motion on an amicus curiae brief submitted by the FDA stating that the agency had already considered and rejected such a warning as unsupported by scientific evidence.⁴⁴

In its amicus brief, the FDA first stated that “because it had considered and rejected an additional suicide warning for Zoloft, a state law prescribed suicide warning would result in misbranding of the drug in violation of federal regulations.”⁴⁵ The district court believed a company could include its own warnings with those approved and provided by the FDA.⁴⁶ However, the FDA contested this belief in its amicus brief. The agency stated that it did not need to specifically disallow any further warnings for preemption to be available.⁴⁷ The FDA also argued that the warning requested by the plaintiff would “frustrate the purposes and objectives of the FDCA.”⁴⁸ Ultimately, the motion for summary judgment was granted and affirmed with neither the trial nor appellate court reaching the preemption issue, but the amicus curiae brief signaled that “the FDA . . . [would] weigh in on the preemption argument and . . . play a more active role in the disposition

39 *Dusek v. Pfizer, Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at *4-6 (S.D. Tex. Feb. 20, 2004).

40 *Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697, at *4 (N.D. Tex. Aug. 6, 2004).

41 *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1087 (C.D. Cal. 2000), *summary judgment granted*, 196 F. Supp. 2d 984 (C.D. Cal. 2001), *aff’d*, 358 F.3d 659 (9th Cir. 2004).

42 *Id.*

43 *Id.* at 1086.

44 *Motus v. Pfizer, Inc.*, 358 F.3d 659, 659-60 (9th Cir. 2004).

45 *Coronato & Lanza, supra* note 23, at 384.

46 *Id.*

47 *Id.* at 384-85.

48 *Id.* at 385.

of these cases in the future.”⁴⁹ The FDA was likely unaware, however, that the *Motus* brief would live on far past the end of the action itself.

C. *Dusek v. Pfizer: Embracing the Brief*

Following the *Motus* case, Pfizer increased its efforts to use the FDA’s brief to achieve summary judgments on all “failure to warn” claims concerning Zoloft and the suicide warning. The first case to accept the defense was the unreported case of *Dusek v. Pfizer, Inc.* in February of 2004.⁵⁰ The district court saw the question in terms of whether the proposed warning by the plaintiff would be considered “‘false’ and ‘misleading’” by the FDA.⁵¹ Citing a “unique set of facts” that distinguished the case from prior cases, the court found that dismissal due to preemption was required.⁵²

The *Dusek* court specifically noted the *Motus* amicus brief and the positions of the FDA taken therein. After noting that United States Supreme Court precedent required weight be given to the amicus brief, the court found support for preemption.⁵³ Because the amicus brief clearly stated the FDA’s decision that a warning requiring the phrase “Zoloft can and does cause suicide in some patients” was not supported by scientific evidence (and application of such would result in misbranding), a state court finding to the contrary would directly conflict with the FDA power to regulate the warning and would therefore be preempted.⁵⁴ The court also stated that the amicus brief was properly given weight even though there was no express preemption clause contained in the FDCA.⁵⁵

Finally, the court held that, although the state courts and the plaintiffs might not agree with the FDA’s assessment, a products liability action against the pharmaceutical company was not the proper venue to challenge their decision. Although previous precedent in *Hurley v. Lederle Labs*⁵⁶ called for a jury question concerning adequacy of disclosure by the pharmaceutical company to the FDA,⁵⁷ the *Dusek* court recognized that the United

49 *Id.*

50 *Dusek v. Pfizer, Inc.*, No. Civ.A. H-02-3559, 2004 WL 2191804, at *1, *5–6 (S.D. Tex. Feb. 20, 2004).

51 *Id.* at *3.

52 *Id.* at *1.

53 See *Dusek*, 2004 WL 2191804, at *5 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000)).

54 *Id.* at *7.

55 *Id.*

56 *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1179–80 (5th Cir. 1988).

57 *Dusek*, 2004 WL 2191804, at *8 (citing *Hurley*, 863 F.2d at 1179). The court stated, “assuming that the FDA has processed all the relevant and available information in arriving at the prescribed warning, its decision as to the proper wording must preempt by implication that of a state[.] . . . [a] factual issue remains . . . as to whether the manufacturer provided the

States Supreme Court had ruled that such "state-law fraud-on-the-FDA" claims were preempted by the FDCA.⁵⁸ Such an ability on the plaintiff's part would cause disclosures to the FDA during the NDA and supplemental phases to become a "deluge of information" and virtually useless to the FDA.⁵⁹

The finding of preemption rested on two key points. First, the *Dusek* court specifically addressed the issue of the ability of pharmaceutical companies to strengthen their warnings prior to FDA approval.⁶⁰ The key to bypassing this impediment is the realization that, while the warning could be supplemented and expanded by the pharmaceutical company, it would still have to be approved by the FDA at some time.⁶¹ Stating that this later approval requirement is intended to prevent misbranding by the pharmaceutical company,⁶² the court found that had the plaintiff simply requested a different form of warning without requiring the causal element between Zoloft and suicide,⁶³ then the defense would have been invalid.

The plaintiff, however, insisted upon the specific verbiage causally connecting Zoloft and suicide that the FDA had previously specifically rejected as false and misleading.⁶⁴ It was this specific contradiction with a separate declaration by the FDA that completed the preemption. Absent this specific statement, and contrary to the assertions of the FDA that it need not specifically disallow a warning for it to be preempted,⁶⁵ there would have been no conflict preventing the plaintiff from proceeding.⁶⁶

In sum, the *Dusek* court found that, due to these specific circumstances, the "FDA's requirements clearly cease to become minimum requirements and become mandatory."⁶⁷ Further, the court likened the instant situation to that of *Geier v. American Honda Motor Co.*⁶⁸ where the United States Supreme Court held that, since Federal Motor Vehicle Safety Standard (FMVSS) 208 specifically allowed car manufacturers to choose between seat belts and/or air bags as required safety devices, an automobile manufac-

FDA with all the necessary and available information on which to base the warning." *Id.* at *8.

58 *See id.* at *8 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)).

59 *Id.*

60 *See supra* note 14 and accompanying text.

61 *Dusek*, 2004 WL 2191804, at *9.

62 *Id.* ("Presumably, this requirement is founded on the principle that the manufacturer may not unilaterally alter a warning under the claim of 'strengthening' its language when in fact the change makes it 'false' or 'misleading.'").

63 *Id.* ("Zoloft can and does cause suicide.").

64 *Id.*

65 *See supra* note 33 and accompanying text.

66 *Dusek*, 2004 WL 2191804, at *9.

67 *Id.*

68 *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 866 (2000).

turer could not be held liable for choosing not to install an air bag if they had properly functioning seat belts installed.⁶⁹ In *Dusek*, the FDA had not merely allowed a choice as in *Geier* but had specifically denied the company from using what the plaintiff claimed was needed. Faced with this special situation,⁷⁰ the *Dusek* court found direct conflict preemption and dismissed the plaintiff's failure to warn claim.⁷¹

Later that same year, the court in *Needleman v. Pfizer, Inc.* agreed with the *Dusek* court on practically the same facts.⁷² Although the *Needleman* case is also unreported, pharmaceutical companies likely hoped that these decisions signaled a trend toward allowing federal preemption in the special circumstances of *Dusek* and *Needleman*. Instead, not only did several subsequent decisions disagree with the *Dusek* and *Needleman* courts, but they did so under remarkably similar circumstances.

D. Cartwright, Zikis, and Witzcak: Disregarding the Brief

In *Cartwright v. Pfizer, Inc.*,⁷³ Bethany Cartwright committed suicide following a round of treatment with Zoloft. Cartwright's family claimed that "Pfizer had sufficient knowledge of the association between Zoloft and acts of self-harm to warn of this association prior to Bethany Cartwright's death and yet failed to warn of this association."⁷⁴ Pfizer again claimed preemption by both the FDA's amicus brief from *Motus* and in general due to the extensive regulation and control that the FDA asserts over the warnings on pharmaceutical products. Instead of following *Dusek* and *Needleman*, the *Cartwright* court found that no preemption existed.⁷⁵

The *Cartwright* court found that Congress' primary goal in enacting the FDCA was "to protect consumers from dangerous products."⁷⁶ Concern-

69 *Dusek*, 2004 WL 2191804, at *9 (citing *Geier*, 529 U.S. at 867).

70 *Dusek*, 2004 WL 2191804, at *10.

While the Court is aware that the majority of district courts facing this issue have declined to find preemption, the facts before this Court are unique. Unlike the record before the other district courts, the FDA has made known its position on the preemption issue through an amicus brief filed with the Ninth Circuit in the *Motus* appeal, and has given the causation issue detailed analysis several times . . . Thus, this Court's holding is a narrow one. The Court does not hold that FDA drug approvals in general preempt failure to warn claims.

Id.

71 *Id.*

72 *Needleman v. Pfizer, Inc.*, No. Civ.A. 3:03-CV-3074-N, 2004 WL 1773697, at *1 (N.D. Tex. Aug. 6, 2004).

73 *Cartwright v. Pfizer, Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005).

74 *Id.* at 878.

75 *Id.* at 887.

76 *Id.* at 882 (citing *United States v. Sullivan*, 332 U.S. 689, 696 (1948)).

ing the extensive regulation and control that the FDA normally exercises over pharmaceutical companies, the court restated that the FDA (and the FDCA in general) only sets "minimum standards with which manufacturers must comply; they *expressly* do not prohibit a manufacturer from 'add[ing to] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction.'" ⁷⁷ The court affirmed that "numerous courts over the years" had followed this line of thought and even noted that the FDA had adopted similar thinking in 1965. ⁷⁸ Furthermore, the "minimum standards approach is . . . consistent with Congress' stated intent that the FDCA 'must not weaken the existing laws', [*sic*] but on the contrary 'it must strengthen and extend that law's protection of the consumer.'" ⁷⁹ If preemption was to be found, special extraneous circumstances would have to be found similar to *Dusek*.

The *Cartwright* court began by examining the same precedent as the *Dusek* court in a different light. It noted that the United States Supreme Court in *Geier* had "limited its conflict preemption holding to the language of the federal regulation at question and stated that 'the language of [FM-VSS 208] and the contemporaneous [agency] explanation is clear enough—even without giving [the agency's] own view special weight.'" ⁸⁰ After noting, as did the *Dusek* court, that the courts have consistently found no preemption in these cases over the years, the *Cartwright* court reaffirmed *Hurley*'s more general principle that "FDA regulation does not generally preempt stricter state law standards for medical products."⁸¹ This line of reasoning helped ensure that more general preemption defenses on pharmaceutical warning labels would not be successful. ⁸²

Finally, the court addressed the issue of the amicus brief by the FDA in *Motus*. First, it noted the portion of the *Motus* brief that said the warning

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.* (citing *United States v. Dotterweich*, 320 U.S. 277, 282 (1943)).

⁸⁰ *Id.* at 883 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 866 (2000)).

⁸¹ *Id.* at 884 (citing *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1179-80 (5th Cir. 1988)).

⁸² *Id.* at 886. Pfizer argued that preemption was appropriate due to (a) interference with the FDA's duty to insure the warnings are scientifically accurate and because (b) the inclusion of scientifically unsupported warnings would "interfere with the FDA's goal of providing patients with the benefit of appropriate medications." *Id.*

Another argument that Pfizer could have tried was that requiring Pfizer to include all types of warnings prior to FDA approval would result in a "deluge of information" that would render the warning useless. By following *Hurley* instead of *Buckman Co.*, Pfizer would not likely have been successful on this argument even had they made it. The court stated, "[c]learly, the FDA through its regulations, recognizes its important dual purpose—to provide scientifically accurate information and to protect consumers—because it allows, and even encourages, manufacturers to be proactive when learning of new safety information related to their drug." *Id.*

would be “in conflict with federal law because there was no (and still is not) scientific support for such a warning.”⁸³ The court found that the plaintiffs had presented evidence to the contrary of the FDA assertions⁸⁴ therefore showing support for such a warning.⁸⁵ Second, the plaintiff did not request a “causal connection” warning between Zolof and suicide but instead sought a warning “regarding the association between suicidality and Zolof—an association that Pfizer has known about for many years.”⁸⁶ The brief was therefore no longer arguably a “clear indication” of federal preemption, and the court ruled against Pfizer on the issue.

Later that year, *Cartwright*’s holding would be echoed in the cases of *Zikis v. Pfizer, Inc.*⁸⁷ and *Witczak v. Pfizer, Inc.*⁸⁸ The *Zikis* court, after asserting that “a court should not find pre-emption too readily in the absence of clear evidence of a conflict,”⁸⁹ found the plaintiff could proceed because her proposed warning simply called for an “association between Zolof and acts of self-harm.”⁹⁰ Furthermore, the court noted that Pfizer’s claims of conflict preemption were “hypothetical potential conflicts” that might have arisen had Pfizer properly altered its warning label.⁹¹ Pfizer responded by stating that actual conflicts existed between the FDA and the proposed warning due to the *Motus* brief. Finding that Pfizer “fail[ed] to point to evidence that shows any tangible conflict,” the court held that preemption failed because Pfizer was attempting to “artificially construct conflicts where none actually exist.”⁹² Furthermore, the amicus brief from *Motus* was nothing more than “legal arguments by counsel” and not precedent.⁹³

The *Witczak* court affirmed the older notion that normal compliance with FDA regulations establishes a floor, and the ability to unilaterally strengthen warnings would not allow preemption to be used. The court also addressed the FDA’s amicus brief from *Motus* and found that a single legal brief from the FDA should not be afforded “preemptive force of

83 *Id.*

84 Plaintiff presented accumulated evidence that tended to indicate an association between Zolof and suicide.

85 *Cartwright*, 369 F. Supp. 2d at 884.

86 *Id.* at 886 n.2.

87 *Zikis v. Pfizer, Inc.*, No. 04 C 8104, 2005 WL 1126909, at *1, (N.D. Ill. May 9, 2005).

88 *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005).

89 *Zikis*, 2005 WL 1126909, at *2 (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 866 (2000)).

90 *Id.* at *3.

91 *Id.* at *2.

92 *Id.* at *3.

93 *Id.*

law.”⁹⁴ Additionally, the court noted that the FDA had “since modified its own position” on the connection between suicide and Zoloft.⁹⁵

By mid-2005, courts were almost universally ruling that the FDA regulations alone would not provide a preemption defense. The specific circumstances surrounding the *Motus* brief had started strong in favor of preemption, but the theory seemed to be waning, especially in light of the FDA’s reevaluation of the class of drug to which Zoloft belonged. The brief was outdated, and nothing new from the FDA was ready to fill the gap. Compounding the problem was a lack of clear indications on how to approach the preemption problem in general.⁹⁶ A complete review and analysis of federal preemption law is far beyond the scope of this Note, but it is sufficient to say that following the *Medtronic, Inc. v. Lohr* decision and the confusion surrounding *Motus*, “[f]ederal preemption jurisprudence [was] even less clear . . . than in the immediate aftermath of . . . *Lohr*.”⁹⁷ Writers for the American Law Institute and American Bar Association stated in August 2005 that “one thing remains certain—the debate will rage on until the Supreme Court steps in and clarifies the doctrine once and for all.”⁹⁸ Although the doctrine is still far from clarified, the United States Supreme Court may have aided the pursuit of a solution with the decision reached in *Bates v. Dow Agrosciences, LLC*.⁹⁹

IV. *BATES V. DOW AGROSCIENCES LLC AND RITE-AID CORP. V. LEVY-GRAY*

A. *Bates v. Dow Agrosciences, LLC: Basic Principles*

Ultimately, *Bates v. Dow Agrosciences, LLC* concerned a statutory scheme only somewhat analogous to the FDCA, a different set of circumstances than most “failure to warn” claims in pharmaceutical products liability litigation, and a clear hesitation to assertively define federal preemption doctrine. Texas peanut farmers sued Dow Agrosciences for violations of the Texas Deceptive Trade Practices Act (“DTPA”) under a variety of theories. One key issue was whether the Federal Insecticide, Fungicide and Rodenticide Act (“FIFRA”) preempted a state tort law claim based on potential false labeling. While the Supreme Court did not decide the issue, its instructions to the lower court on remand likely barred the use of preemption in that case,¹⁰⁰ and the dicta on the issue is instructive for

94 *Witzak v. Pfizer, Inc.*, 377 F. Supp. 2d 726, 730 (D. Minn. 2005).

95 *Id.*

96 Coronato & Lanza, *supra* note 23, at 384.

97 *Id.* at 389.

98 *Id.* at 390.

99 *Bates v. Dow Agrosciences, LLC*, 544 U.S. 431 (2005).

100 The case was remanded for further determination.

projecting how future pharmaceutical products liability preemption claims will be treated.

The FIFRA regulations governing the claim in *Bates* involve a misbranding of the product similar to the misbranding provisions of the FDCA, but there are several key differences. The requirements that the Environmental Protection Agency (EPA) has in place for evaluating the labeling of products under FIFRA are much less stringent than the FDA's regulations for prescription drug labeling. For instance, the EPA issued a notice in 1996 that announced it no longer "evaluat[ed] pesticide efficacy for routine label approvals," and it had not done so for over two decades.¹⁰¹ This notice also clearly stated that the "EPA's approval of a pesticide label does not reflect any determination on the part of the EPA that the pesticide will be efficacious or will not damage crops or cause other property damage," and "pesticide producers are aware that they are potentially subject to damage suits by the user community if their products prove ineffective in actual use."¹⁰²

Further, an express preemption provision was contained in FIFRA, which stated, "[s]uch State [that regulates the sale or use of any federally registered pesticide or device in the State] shall not impose or continue in effect any requirement for labeling or packaging in addition to or different from those required under this subchapter."¹⁰³ The Court held that preemption would only exist if a rule was for both labeling and packaging and imposed a requirement in addition to or different from those required by FIFRA.¹⁰⁴ The Court also found that a rule that motivated an optional decision would not qualify as a requirement and that while common-law duties could be considered "requirements," the common-law duties would have to specifically address labeling or packaging for them to potentially have preemptive effect. Therefore, a claim based on design defect, manufacturing defect, or express warranty breach would not be affected by such a preemption provision.¹⁰⁵ It should be noted that a "failure to warn" claim likely would be affected.

Bates v. Dow Agrosciences, LLC provided evidence that allowing common-law suits would provide a "crazy-quilt" of standards, different in every state, that manufacturers would need to meet in addition to the federal standards in order to avoid liability.¹⁰⁶ The Court found the issue to be "exaggerate[d]," and that "no evidence [showed] that such tort suits . . .

¹⁰¹ *Bates*, 544 U.S. at 440.

¹⁰² *Id.* (citing EPA Pesticide Registration Notice 96-4, at 3, 5 (June 3, 1996)).

¹⁰³ 7 U.S.C. § 136v(b) (2000).

¹⁰⁴ *Bates*, 544 U.S. at 444.

¹⁰⁵ *Id.* at 444–45.

¹⁰⁶ *Id.* at 448.

[would] create[] any real hardship for the manufacturers or the [regulatory agency]."¹⁰⁷

Finally, the *Bates* Court distinguished the instant case involving herbicides from the decision of *Cipollone v. Liggett Group, Inc.*¹⁰⁸ involving cigarettes. *Cipollone* addressed the issue of cigarette package labeling in terms of recently passed legislation addressing cigarettes specifically instead of the general provisions of the FDCA. Congress had passed extensive legislation on cigarette packaging, and the state was prevented from deviating from this legislation. The *Bates* Court stated:

Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA. Unlike the cigarette labeling law at issue in *Cipollone*, which prescribed certain immutable warning statements, FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings [T]ort suits can serve as a catalyst in this process. . . .¹⁰⁹

The FDCA more closely resembles FIFRA than it does the tobacco legislation at issue in *Cipollone*. There are no fixed, immutable warnings for all of the various pharmaceutical products in the market; instead, it is contemplated that each product is different, and that due to the product being on the cutting edge of science, the manufacturer's knowledge of the effects of the drug will change over time as the drug encounters different people in different environments and different situations.

Because of this instability of the pharmaceutical market, the *Bates* decision could be read to support the idea that, because the pharmaceutical manufacturers will be the first ones to gain this knowledge (as opposed to the FDA or other administrative body), these manufacturers should be liable in tort for damages caused, as they will be in a better position to unilaterally strengthen or add to their warnings under the FDCA. Declarations by the FDA, however, might provide the extensiveness (similar to the tobacco legislation in *Cipollone*) that would allow preemption. The declaration would also cement the federal requirement with which the "failure to warn" claim would be conflicting.¹¹⁰ Ultimately, this simply reinforces the idea that no preemption should exist in normal pharmaceutical "failure to warn" tort cases that lack "something extra," like the *Motus* brief.

¹⁰⁷ *Id.* at 451-52.

¹⁰⁸ *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992).

¹⁰⁹ *Bates*, 544 U.S. at 451.

¹¹⁰ See *supra* note 89 and accompanying text.

B. Rite-Aid Corp. v. Levy Gray and Applying the Principles of Bates

A subsequent decision addressed the implications of *Bates* in the pharmaceutical context in May 2005.¹¹¹ In *Rite-Aid Corp. v. Levy-Gray*, the court found *Bates* to be inapplicable to the instant situation, as it centered on express warranty.¹¹² However, *Rite-Aid* did provide at least one court's view on the preemption defense after *Bates*. The landscape does not appear to have changed, and the court determined that preemption was not available based solely on compliance with FDA regulations. It did not address the *Motus* situation.

The *Rite-Aid* court moved swiftly through the normal preemption arguments and found that there was no express preemption provision, thus relegating the defendants to attempt a showing of implied preemption. The court dismissed implied direct and field preemption, as there was no real "conflict" in the court's mind between the warning label and the state tort law (and accompanying suggested warning by the plaintiff); nor was there a comprehensive regulatory scheme established that provided for exclusive regulation in light of Supremacy Clause jurisprudence.¹¹³ *Rite-Aid* sought to rely on implied preemption through obstruction of a federal purpose, but the court maintained that such preemption was inapplicable as "demonstrated by the many cases upholding state law products liability claims against pharmaceutical manufacturers whose labels have been FDA approved."¹¹⁴

Further, the court noted the *Ehlis v. Shire Richwood* decision, but it stated that the ruling was not controlling, as *Ehlis* was ultimately affirmed on alternative grounds without the appellate court having ever reached the issue of federal preemption. The court also mentioned *Needleman* and *Dusek* in a footnote, but it noted that the underlying rationale from the *Motus* brief was never validated, as the Ninth Circuit affirmed the dismissal of the claim in *Motus* without ever having reached the issue of preemption.¹¹⁵ The court did hold that compliance with the FDA standard would allow for an inference of product safety, but the inference was clearly rebuttable and did not extend to the point of preemption.¹¹⁶

So where did this leave the preemption defense? Although the *Rite-Aid* court affirmed the normal "no preemption based on compliance with FDA regulations" argument, it did not directly apply any of the *Bates* principles to a specific and timely *Motus* situation. It negated the impact of the *Motus*

¹¹¹ *Rite-Aid Corp. v. Levy-Gray*, 876 A.2d 115 (Md. Ct. Spec. App. 2005), *aff'd*, 894 A.2d 563 (Md. 2006)

¹¹² *Id.* at 133.

¹¹³ *Id.* at 130.

¹¹⁴ *Id.* at 131.

¹¹⁵ *Id.* at 133 n.10.

¹¹⁶ *Id.* at 133–34.

brief by showing the final decision in *Motus* did not rest on the amicus brief itself, and it dismissed *Needleman* and *Dusek* for the same reason. It did not, however, adequately address whether the issue of a valid *Motus*-styled amicus brief would provide federal preemption of a state tort "failure to warn" claim. Aside from what inferences we can gather from *Bates*, it appears that the law was left in the same unresolved state it was in when the *Motus* case was originally dismissed.

V. THE FDA'S STANCE WITH THE NEW REGULATIONS AND THE AMICUS OPTION

The FDA issued a new rule on January 18, 2006, that was designed to overhaul the labeling that accompanies prescription drugs for the first time in twenty-five years.¹¹⁷ One aim of the new regulation was "to simplify labels that had become complex legal disclaimers" in response to state tort "failure to warn" actions.¹¹⁸ Pharmaceutical manufacturers during the promulgation of this rule had become very concerned that the elimination of the complex warnings would result in increased liability, and the companies raised these concerns to the FDA during commentary on the proposed rule. The FDA responded by including language in the preamble to the rule that stated "an FDA-approved label 'whether it be in the old or new format, preempts conflicting or contrary state law, regulations, or decisions of a court of law for purposes of product liability litigation.'"¹¹⁹ The FDA addressed the inclusion of the new preamble language in its response commentary when republishing the proposed rules.

First, the FDA emphasized their status as the "expert Federal public health agency charged by Congress with ensuring that drugs are safe and effective, and that their labeling adequately informs users of the risks and benefits of the product and is truthful and not misleading."¹²⁰ It also stressed the approval procedures required by the FDA for supplementing warnings, specifically noting and endorsing the *Ehlis v. Shire Richwood* decision and dismissing decisions that found no federal preemption as a result of procedures. The FDA stated that although a "manufacturer may, under FDA regulations, strengthen a labeling warning . . . in practice manufacturers typically consult with [the] FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action)."¹²¹

¹¹⁷ Diedra Henderson, *FDA Rule May Aid Drug Firms in Liability Suits*, BOSTON GLOBE, Jan. 19, 2006, at D4.

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified at 21 C.F.R. § 201.56).

¹²¹ *Id.*

Next, the FDA found that “[a]nother misunderstanding of the [FDCA] encouraged by State [*sic*] law actions is that FDA labeling requirements represent a minimum safety standard.”¹²² The agency dismissed the theory of state tort law acting as an “appropriate source of supplementary safety regulations” for prescription drugs, and it found that the FDCA mandated that its regulations and labeling requirements established both a “floor” and a “ceiling.”¹²³ The “comprehensiveness of FDA regulation[s]” made “additional requirements for the disclosure of risk information” not necessary for the protection of patients.¹²⁴ The FDA admitted that the act “itself contains no general express pre-emption [*sic*] provision for drugs,” and even noted that in an amendment to the FDCA in 1962 Congress seemed to expressly deny preemption,¹²⁵ but the FDA maintained that the “existence of a legislative provision addressing pre-emption [*sic*] does not bar the operation of ordinary principles of implied preemption.”¹²⁶

¹²² *Id.*

¹²³ *Id.* at 3934–35.

¹²⁴ *Id.* Indeed, the FDA noted the problems that arise when allowing state tort law to require warnings different from the FDA:

[State law decisions] can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug

State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterized by centralized expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public—the central role of the FDA—sometimes on behalf of a single individual or group of individuals. That individualized reevaluation of the benefits and risks of a product can result in relief—including the threat of significant damage awards or penalties—that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose ‘defensive labeling’ to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warning and underutilization of beneficial treatments.

Id.

¹²⁵ Kefauver-Harris Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) provides:

Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provisions of State law.

¹²⁶ Requirements on Content and Format of Labeling for Human Prescription Drug

The FDA then applied the above assertions and principles to the potential state tort law claims based on prescription drugs. The agency found six claims that it maintains are preempted by the labeling requirements that it promulgates under the FDCA:

- (1) Claims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling;
- (2) Claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug's sponsor has used Highlights consistently with FDA draft guidance regarding the "brief summary" in direct-to-consumer advertising;
- (3) Claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including 201.57(c)(5) (requiring that contradictions reflect "[k]nown hazards and not theoretical possibilities") and (c)(7);
- (4) Claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusions in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation);
- (5) Claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA had prohibited in labeling or advertising; and
- (6) Claims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA had made a finding that the sponsor withheld material information relating to the statement).¹²⁷

The FDA also asserted that the claims would be preempted not only against manufacturers of the prescription drugs but also against "health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling."¹²⁸ The agency also recognized not all state law actions would be preempted by the regulations. For instance, the FDA recognized the *Medtronic, Inc. v. Lohr* decision that held state law requirements that parallel FDA requirements may not be preempted.¹²⁹ Finally, the FDA reiterated the *Buckman Co. v. Plaintiff's Le-*

and Biological Products, 71 Fed. Reg. 3922-01, 3935 n.8 (2006) (citing *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

gal Committee holding that “state-law fraud-on-the-FDA” claims were preempted by Federal law, enforceable only by suits brought by the United States.¹³⁰

Following these assertions by the FDA, the immediate responses by the various affected groups varied considerably. Joan Claybrook, president of Public Citizen, a national non-profit public interest organization, called the preamble’s statements both “a sneak attack on consumer rights” and illegal, as the FDA does not have the “congressionally mandated authority to preempt state law.”¹³¹ The National Conference of State Legislatures (NCSL) also argued that the FDA has “no statutory authority in the FDCA . . . to preempt state product liability laws as they relate to prescription drugs.”¹³² Further, the NCSL believes that the FDA’s prescription drug regulations only provide a minimum “floor” consistent with a majority of judicial opinions on the regulations, and it also contends that the regulations violate Executive Order 13132¹³³ and agency law.¹³⁴ Several democrats in the United States House of Representatives and Senate denounced the statements as a “boost to pharmaceutical makers by offering them protection from lawsuits from patients who are injured by their products,” and they maintained that they would seek ways to legislatively block the new rule before it went into effect on June 30, 2006.¹³⁵

The FDA itself declined to say that its statements are anything but a statement of policy. On at least one occasion, it declared that the statements were nothing more than a reiteration of its long-held policy on preemption, a view that it has stressed in several amicus briefs (including *Motus*). Scott Gottlieb, FDA deputy commissioner for medical and scientific affairs, stated that the “language is in the preamble, not the codified section of the rule and whether or not individual courts take it into consideration is up to

¹³⁰ *Buckman Co. v. Plaintiff’s Legal Comm.*, 531 U.S. 341, 348 (2001).

¹³¹ Press Release, Public Citizen, FDA’s Drug Label Rule Fails to Guarantee Access to Vital Information and Includes ‘Sneak Attack’ on Patients’ Legal Rights (Jan. 18, 2006), <http://www.citizen.org/pressroom/release.cfm?ID=2114>.

¹³² Press Release, Nat’l Conference of State Legislatures, Proposed FDA Rule Preempts State Product Liability Laws (Jan. 13, 2006), <http://www.ncsl.org/programs/press/2006/pro60113.htm>.

¹³³ Executive Order 13132 requires that the federal government first consult with state and local governments before finalizing rules that present potential conflict between state and federal law, which NCSL maintains the FDA did not do in this case. *See* Exec. Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999); Timothy Ardizzone, Note, *The FDA: Advocate or Regulator of the Pharmaceutical Industry? The Attempted Preemption by the FDA of State Tort Claims for Failure to Warn on Pharmaceutical Labeling*, 75 U. CIN. L. REV. 763, 783–84 (2006).

¹³⁴ The NCSL maintains that it is a violation of the Administrative Procedures Act (APA) for the FDA to not reopen its comment procedure to address this issue. *See* Press Release, *supra* note 132. The FDA maintains that it has satisfied the APA on this regard.

¹³⁵ *Senate Democrats May Block FDA Rx Labeling Rule with Legislation*, FDA WEEK, Jan. 20, 2006, 2006 WLNR 1097774 [hereinafter *Democrats May Block Labeling Rule*].

them.”¹³⁶ The FDA has since extended this “long-held” view to other areas besides prescription drugs, including over-the-counter medication in spite of a provision in the FDCA to the contrary.¹³⁷

A significant issue has been raised as to the authority commanded by the statements in the preamble, and a ruling on this issue will obviously control the shape of the FDA compliance defense. The views of the FDA differ greatly from the judicial interpretations of nearly every court that has considered the issue, even the more receptive views of *Dusek* and *Needleman*. The FDA cites *Ehlis* as an example of the “preemption by labeling only” argument that it makes, but it is interesting to note that nearly every court that has considered the same issue has disregarded the ruling. If the FDA’s opinion has valid legal weight, the federal preemption doctrine would change drastically.

As the FDA has admitted, however, the language is contained solely in the preamble instead of the codified section of the rule, and the agency feels that the final decision as to whether or not preemption actually exists is to be left up to the individual courts.¹³⁸ As the courts have consistently rejected the view that the FDA regulations standing alone provide a preemption defense, it is highly unlikely that the most recent statements by the FDA will have any more impact than the other attempts by the FDA. Although the preamble statements may influence the courts to lean towards a more favorable view on preemption, the status of federal preemption of state tort law claims will rest with a final resolution between the principles demonstrated in *Dusek* and *Needleman* and the negative cases like *Cartwright*, *Zikis*, and *Witzak*.

While the current state of an “FDA compliance” preemption defense is not completely solidified in the eyes of the judiciary, there are several concepts that appear to have reached a general level of consensus. Despite the FDA’s assertions to the contrary, compliance with the FDA labeling provisions alone will not allow a pharmaceutical company to obtain preemption. While the structure and implementation of the portions of the FDCA concerning drugs are very extensive and thorough, and the FDA has consistently and recently proclaimed the regulations to be preemptive of state tort law requirements, there does not seem to be enough support either at the United States Supreme Court or at the lower levels of the judicial system to overturn this view. Absent the addition of an express preemption provision similar to that pertaining to medical devices, pharmaceutical drug

¹³⁶ *Id.*

¹³⁷ *Bradshaw Says FDA Preempts State Tort Laws on OTC Drugs*, FDA WEEK, Feb. 3, 2006, 2006 WLNR 1921073 (citing Food, Drug and Cosmetics Act § 751: “Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.”).

¹³⁸ *Democrats May Block Labeling Rule*, *supra* note 135.

manufacturers will not be able to rely on an approved warning by the FDA alone.

What is less clear is whether a specific statement by the FDA will be allowed to provide a preemption defense for the pharmaceutical companies. Cases such as *Cartwright*, *Witczak*, and *Zikis* sought to override the principles of the unreported cases of *Dusek* and *Needleman*, and although a vast majority of other jurisdictions have followed suit, the actual validity of such a defense has not yet reached the Supreme Court. One reason for the lack of support for the *Motus* brief in the later cases, although not mentioned, could likely have been the span of time between the original filing of the amicus brief and the date of the rising of the cause of action in each case. The brief itself was filed in 2000. In *Dusek* and *Needleman*, the incidents in question occurred in early 2000 and 2002. In *Cartwright*, *Witczak*, and *Zikis*, the incidents occurred in the latter half of 2002, 2003, and 2005, respectively. The plaintiff in *Cartwright* altered its suggested warning to conform to some of the issues that the *Dusek* court identified with the preemption defense, and the court found that the *Motus* brief was no longer indicative of the FDA's view because the plaintiff presented evidence that new support for a finding of scientific validity concerning the connection between Zolof and suicide had surfaced. This change in circumstances damaged the credibility of the *Motus* brief, and the *Witczak* court noted that the FDA "has since modified its own position" regarding the causal connection.¹³⁹ This view makes sense as more evidence was uncovered linking the type of drug under which Zolof was classified with suicide in a variety of situations.

Naturally, the next question is where should the defense go from here? Following *Dusek*, several different theories emerged. Diane Lifton¹⁴⁰ and Michelle Bufano¹⁴¹ advocated a complete FDA compliance system¹⁴² similar to the one codified in Michigan.¹⁴³ Lifton and Bufano cited the heavy regulation by the FDA of the application and post-surveillance process and that the manufacturer's ability to alter the label was more limited than what the statutes seemed to imply.¹⁴⁴ The recent FDA preamble statements obviously show that the FDA would support Lifton and Bufano's view. Lifton and Bufano wrote this article prior to *Cartwright*, *Zikis*, and *Witczak*, and

¹³⁹ *Witczak v. Pfizer, Inc.*, 377 F. Supp. 2d 726 (D. Minn. 2005).

¹⁴⁰ Diane E. Lifton is a Director of Gibbons, Del Deo, Dolan, Griffinger & Vecchione, PC and co-chair of the Pharmaceutical Medical Devices and Laboratory Practice Group of the same firm. Lifton & Bufano, *supra* note 2, at 1.

¹⁴¹ Michelle M. Bufano is an Associate at Gibbons, Del Deo, Dolan, Griffinger & Vecchione, PC and specializes in pharmaceutical and medical device claim defense. Lifton & Bufano, *supra* note 2, at 1.

¹⁴² Lifton & Bufano, *supra* note 2, at 1.

¹⁴³ MICH. COMP. LAWS ANN. § 600.2946(5) (West 2006).

¹⁴⁴ Lifton & Bufano, *supra* note 2, at 1.

the reaffirmation of the inability to rely simply on the normal codification procedures seems to have refuted the possibility of the judicial system approving such a method. While the legislature could remedy the problem and allow for such an easily obtainable and absolute defense, the general lack of state legislation on the subject and the repeated refusal by Congress to add an express preemption clause to the FDCA indicates that this is unlikely. Either a new system would need to be proposed, or a variation on the preemption idea behind the *Motus* brief would need to gain support.

Catherine T. Struve, an assistant professor at University of Pennsylvania Law School, proposed a hybrid *qui tam* system that would practically allow the FDA to act as supreme expert witnesses concerning product safety and causation.¹⁴⁵ Her system would also perform a secondary role as a warning system for the FDA for products that suddenly incur large amounts of litigation, indicating that an extensive review of that product would be necessary.¹⁴⁶ She recognized that the current post-market surveillance system of the FDA does not adequately investigate each pharmaceutical product, so an expert witness function fulfilled by the FDA would allow the agency to quickly update its knowledge of the product and then render an opinion that carried the weight of law. In order to fulfill this idea, though, additional legislation would be required, and a fairly extensive "opt in" system would need to be established.¹⁴⁷ As already noted, legislatures have been extremely slow to act on this issue, and the reticent nature of Congress on this subject indicates that while this method may have appeal, the likelihood of its enactment is very slim.

As an alternative to the fully and partially codified systems of Lifton, Bufano, and Struve, the courts could simply expand on the theories of *Dusek* and *Needleman*. The FDA would file an amicus brief, particularly in situations that involved numerous cases filed on virtually identical claims (like the Zolof cases involving Pfizer or the burgeoning Vioxx cases filed against Merck). This brief, as in *Motus*, would contain the FDA's view on the current required warning for the drug and whether the plaintiff's proposed deficiency conflicts with that warning. The FDA has already expressed an interest in filing amicus briefs in exactly this nature,¹⁴⁸ and while this would not allow total federal preemption by labeling alone, it would provide the same kind of liability oversight that the FDA wants to give to the pharmaceutical companies subject to the new regulations. This function would not require any additional legislation, and as it would not require the FDA to make a legal ruling (as the *qui tam* system proposed by Struve would), it would not place on the FDA a duty with which it is inexperienced. The

¹⁴⁵ Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 YALE J. HEALTH POL'Y L. & ETHICS 587 (2005).

¹⁴⁶ *Id.* at 592-93.

¹⁴⁷ *Id.* at 656.

¹⁴⁸ Coronato & Lanza, *supra* note 23, at 390 n.5.

FDA has recognized that its regulatory system surrounding the pharmaceutical sector has not been adequate, and it recently overhauled the system in order to make it much more efficient, less prone to error, and less expensive. With this new system, the FDA will be better able to monitor the pharmaceutical industry and render accurate, timely briefs for litigation and advisory purposes. Further, any increase in manpower and surveillance to give adequate examination to prescription drugs subject to litigation could be fulfilled by smaller units dedicated to more intensive research as legal problems concerning the drugs surface.

Ultimately, one of the best supportive reasons for using the modified amicus brief system would be that it can be implemented now without any significant changes in legislation or policy. The legal precedent for accepting this style has already been established in *Dusek* and *Needleman*, although it would require a shift in thinking in a majority of jurisdictions. The implementation would be virtually the same as *Motus*, only with notification given to the FDA and a request for such a brief to be filed. The decision would be made during the summary judgment phase, reducing cost and administrative effort on the part of the FDA and not causing as large a disruption in the judicial process as the *qui tam* system would mandate. The briefs would either be effective for some time, or they would be easily updated by the FDA when new information arose.

VI. CONCLUSION

The preemption of prescription drug litigation has been a long, heavily traveled road that has not produced much success for the pharmaceutical industry. Despite FDA assertions to the contrary, the concept of relying solely on the regulation of the industry by the FDA for preemption is practically settled and disregarded in all jurisdictions, and only the question of direct FDA interaction for solely preemptive purposes remains. Although the *qui tam* system likely would be effective, the legislation and policy changes it would require will likely never be met with success, especially given the attitude devoted to the area as a whole by both state and national legislatures. The amicus system, as applied in *Dusek* and *Needleman*, should be applied to allow the FDA to fulfill its statutory duty of ensuring safety in the industry while eliminating from the judicial system those cases in need of federal preemption. The courts and the FDA currently have what they need to begin using this system, and they should start now.

